831458 – Trials@Home

Center of Excellence – Remote Decentralised Clinical Trials

WP6 – PROMS

D6.7 Integrated set of recommendations, draft EU Guidelines and (educational) tools to facilitate RCDT implementation in Europe

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Document History

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Abstract

The Trials@Home consortium investigated how clinical trials can transition from traditional site-based models to Decentralised Clinical Trials (DCTs), bringing research closer to participants through digital and operational innovations. This approach reduces or eliminates the need for visits to clinical trial centres, and therefore offers the potential for improving accessibility and participant experience.

The project focused on defining best practices for DCTs, identifying and evaluating technologies and operational strategies, and conducting RADIAL—a pan-European proof-of-concept study comparing fully decentralised, hybrid, and conventional trial designs. In addition, Trials@Home analysed ethical, regulatory, legal, and organisational factors influencing DCT adoption, engaged stakeholders, and disseminated findings through targeted communication and training.

The outcomes include an integrated set of recommendations to support the implementation of DCTs across Europe, contributing to the evolution of international standards such as ICH guidelines. All recommendations are available on the upgraded project website https://trialsathome.com. This deliverable provides an overview of the main recommendations, the more specific recommendations per theme, and the course materials.

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Integrated set of recommendations to facilitate DCT implementation in Europe

Based on six years of multistakeholder scientific research on opportunities and challenges of decentralised clinical trials (DCTs), the Trials@Home consortium has developed a set of main recommendations covering the methodological, regulatory, ethical, operational and social aspects of DCTs. By nature, these main recommendations are high level, and we encourage readers to go to the different content pages on https://trialsathome.com for more practical, detailed recommendations.

1. **Engage stakeholders during trial design to identify activities to decentralise**

Involve patient representatives from the intended study population, as well as research staff and other stakeholders early in the design phase of a trial to determine which trial activities could benefit from a decentralised approach. Keep in mind the research question that the trial aims to answer, and the burden of activities for participants and research staff. Consider that these may change if an activity is decentralised. For example, taking a finger prick blood sample at home is a different burden than going to a lab for a blood draw.

2. **Assess and communicate clearly what is expected from participants to support engagement and fair compensation**

Make a thorough and clear assessment of what is expected from participants in a trial with decentralised elements. These expectations should cover activities to perform, data to collect, digital literacy skills and time spent. Translate this to ensure clear communication with future participants so that they understand what is being asked of them and to ensure fair reimbursement beyond visits and travel reimbursement, especially when they do not need to travel to a site (as often). Our research found that patients prefer DCTs, but at the same time, any added burden or challenges with implementation can negatively impact their experience.

3. **Evaluate decentralised elements and advocate for ethical and regulatory acceptability**

Assess each decentralised element individually, not only regarding risks but also regarding the potential benefits for participants. This assessment should go beyond direct therapeutic benefits and include evaluation of patient and site fit as well as local and global feasibility and clinical trial authorisation. Harmonising of implementation of regulations at the national level by Health Authorities (HAs) and Ethics Committees (ECs) across the EU is needed, while hampered by local laws and regulations. HAs and ECs should however facilitate clarity on local variations in Europe, such as through updating regularly the HMA EMA Recommendation paper on decentralized elements in clinical trials. This allows for conduct of DCTs in a more clear and efficient way, taking into consideration the most suitable approach in each country.

4. **Assess site capabilities and provide tailored training, support and compensation**

Evaluate a site's previous DCT experience and capabiliy to identify any training needs, support or gaps to be addressed prior to implementation, as well as tailored, just-in-time training particularly for novel digital tools and centralised support infrastructures (e.g., help desks and oversight teams during trial conduct). Customisation of regional or national clinical trial agreement templates to accommodate decentralised activities could benefit contracting timelines. Fair site compensation for decentralised efforts should be implemented during contracting.

5. **Select and test technologies early, and embed robust support and governance systems**

Designing and executing DCTs which include technologies requires a strategic, system-level approach that prioritises early technology selection, modular integration, and rigorous end-to-end testing. Incorporate practical measures such as structured bring your own device (BYOD) validation, real-world pilot phases, fallback workflows, and dedicated cross-vendor support systems (e.g., help desk). Clear governance processes, including scalable change management and continuous user feedback loops, are essential to maintain study compliance and ensure a resilient DCT setup. Future trials should embed these principles from the outset to reduce disruption and improve scalability.

6. **Establish participant-centred communication platforms and provide responsive support**

Enable participant-centred communication ecosystems; because participants are expected to perform more tasks independently at home in DCTs, it is essential to provide additional support. In addition to providing clear and accessible information for participants, researchers should implement participant-friendly communication platforms that support real-time dialogue, asynchronous messaging, and tailored guidance. By offering centralised support to participants, some of the burden on site staff can be reduced, allowing them to focus on their core responsibilities. Prioritising responsive, empathetic, and technology-enabled support can empower participants to carry out trial activities confidently and effectively, enhancing engagement, trust and data quality in DCTs.

7. **Plan and test decentralised logistics to mitigate risks and ensure operational readiness**

Assess any new operational and logistical processes that are needed prior to implementation so that the proper risk-mitigation strategies can be planned, which will enable all parties to quickly deal with hurdles in these processes. These include selecting multiple decentralised sites in one country to mitigate risks of under-

recruitment and under-performance and providing multiple reliable options for biological sample collection to improve data completeness. Optimisation of material management and logistics is recommended by implementing just-in-time deliveries to participants' homes to minimise storage requirements, clearly define importation/exportation responsibilities, and conduct comprehensive end-to-end dry runs to identify logistical vulnerabilities before trial initiation.

8. Define roles and responsibilities clearly and ensure oversight mechanisms are in place

Ensure additional specificity around roles and responsibilities because data collection, biological sample collection, and other procedures may be performed through non-traditional routes and involve participants and third-party vendors as the actors more often. Sites need to have access to all data required to maintain oversight and roles and responsibilities. Communication channels also need to be clearly defined before start of the trial.

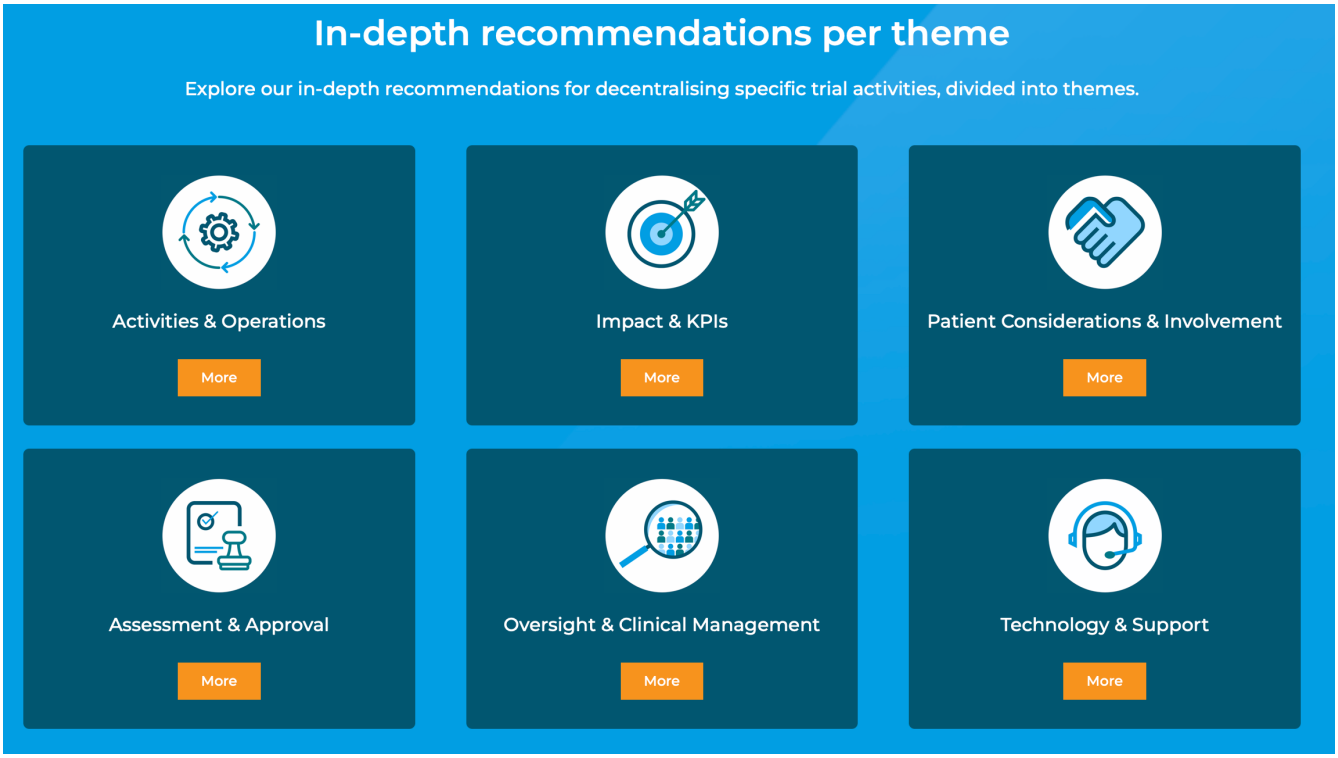
9. Implement rigorous data protection strategies and ensure secure digital infrastructures.

Implement comprehensive data protection strategies that include early risk assessments, clear vendor responsibilities, secure data flows, and adherence to relevant regulations (e.g., GDPR). DCTs in general include an increased use of digital tools, remote data collection, and third-party technologies compared to site-based trials. This requires enhanced attention to data privacy and security. Special care must be taken when using participant-owned devices and cloud-based systems to ensure confidentiality, integrity, and auditability across the trial lifecycle.

Overview of the in-depth recommendations per theme

The Trials@Home consortium divided the in-depth recommendations over six themes: activities & operations, impact & KPIs, patient considerations & involvement, assessment & approval, oversight & clinical management, and technology & support. Within each of the themes, there are two to six subtopics, each with its own page with a brief introduction, the recommendations specific to the subtopic, an explanation of the work performed by Trials@Home leading to these recommendations, and a further reading section with relevant resources from the project.

In this section, we will provide an overview of all recommendations per theme and subtopic.



Activities & Operations

Best practices for DCT approaches

- **Answer an important research question.**

All clinical trials should aim to answer important questions that help patients and healthcare professionals make informed decisions in the future.

- **Keep the focus on participants.**

Researchers should always consider the safety, needs, and preferences of the people taking part in a trial.

- **Simplify the participant experience whilst maintaining quality and scientific rigour.**

Researchers should make it as simple as possible to take part in a trial without compromising the ability of the trial to answer the research question.

- **Involve stakeholders early.**

Everyone involved in making a trial happen, from healthcare professionals and patient groups to those responsible for approving trials and new medicines, should be involved in discussions about the trial plans early, so that their opinions and advice can be taken into account.

- **Share knowledge and experiences.**

Some DCT approaches are still relatively new, and we can learn how to use them more effectively if we share our experiences, challenges, and solutions.

- **Research implementation and improvement of DCTs.**

We should use scientific methods to learn more about when and how DCT approaches work best so that we can improve trials in the future.

- **Design trials for ease of participation and conduct.**

It is not just participants who benefit from simpler trials; the staff who work on trials can do their jobs better when trials are designed with them in mind.

- **Test processes, devices, and software thoroughly before deployment.**

DCTs can be complicated and involve many technological and organisational aspects. All aspects, both technical and logistical, must be tested to check that they work before the trial starts.

- **Facilitate dialogue between participants and researchers.**

In addition to providing participants with information in a way they can understand, researchers should also make it easy for participants to communicate with trial staff and access support during the trial, so that they feel confident in carrying out trial activities at home.

- **Build trusting relationships.**

DCT approaches can involve many different people, and they need to work well together. It is worthwhile to take the time to build trust among those involved in different aspects of the trial.

- **Plan for effective communication between trial personnel.**

Clear communication becomes even more important when there is less in-person contact. Careful planning of communication methods and timing can make things run more smoothly, both for routine trial activities and when unexpected events occur.

- **Agree roles and responsibilities.**

Everyone involved in a DCT has a role, from participants remembering to complete questionnaires to the person responsible for ensuring that blood samples arrive in the laboratory on time. Knowing who is responsible for what and when ensures that tasks are not overlooked and that participants are kept safe.

- **Consider site readiness for DCT approaches.**

DCT approaches are still new to many healthcare professionals. Anyone planning a DCT needs to ensure that all the staff working on it will be appropriately trained and supported for any new ways of working.

- **Plan for the unexpected.**

No matter how well-designed a DCT is, external events like changes to laws and regulations, problems with delivering trial materials, or even global pandemics should be prepared for.

- **Allocate sufficient resources.**

Some people have suggested that DCTs should be less expensive than conventional clinical trials because they require fewer staff and fewer clinic sites. However, our research shows that DCTs may still need a lot of resources to ensure that everything works, that medications and trial materials are where they need to be at the right time, and that everyone involved has the training and support they need.

DCT approaches

- **Choose which approach to use depending on the research question and the participant population.**

The choice of approach to be used in a trial should be informed by the needs of the participants, the clinical sites, and the research question under investigation. Requirements may differ in different participant populations and at different clinical sites. It may not be possible to use DCT approaches for all aspects of the trial.

- **Simplify trial activities for participants by integration of systems.**

This requires a thorough evaluation during the set-up of the trial on whether integration is possible, especially in settings where device or technology-specific data flows are already established.

- **Assess each DCT approach individually.**

Each decentralised element under consideration for inclusion in a trial should be individually assessed to ensure it is permitted in the participating countries, suitable and acceptable for the target study population and trial sites, and technically feasible given existing infrastructure and operational requirements (e.g., continuous broadband internet access).

Remote recruitment and (pre-)screening

- **Tailor recruitment for DCTs to the population.**

A mixed recruitment strategy would likely be most effective, combining online methods such as social media and search advertising to generate broad awareness, and database outreach and healthcare provider referrals to target specific populations.

- **Select multiple decentralised sites in each country.**

Although theoretically a single decentralised site could recruit participants from any place in an entire country, if that site for any reason encounters challenges in the recruitment, this can be very hard to mitigate. Selecting multiple sites mitigates risks of under-recruitment and under-performance.

- **When using online recruitment, prioritise search engine advertisements.**

Our data suggest that paid search drove more pre-screener completions, while performance max campaigns had a high volume but low engagement. Additionally, targeted keyword strategies in search advertising, aligned with condition-specific search behaviour, are essential to improve the relevance and efficiency of recruitment efforts. Future research should aim to understand the search behaviour of potential participants and further explore paid search to attract users actively searching for trial-related information.

- **Simplify and optimise pre-screening consent language and flow to reduce participant drop-off.**

The RADIAL trial found that 69% of candidates abandoned pre-screening at the initial data-processing consent step. To address this, future studies should design pre-screening processes that balance robust eligibility checks with clear, accessible, and participant-friendly privacy explanations. Sponsors should test and refine consent language to make it simpler and less intimidating, reducing anxiety about data use. User-testing consent steps can ensure they are understandable and minimise early attrition, supporting smoother progression through pre-screening.

- **Reimburse remote participants for their time, travel, and effort.**

This includes covering travel to drop-off points or other necessary locations, even though they do not travel to the site. Plan for patient reimbursement in future trials to enhance participation and retention.

Remote consent

- **Standardise informed consent requirements across countries.**

We advocate for clearer, harmonised regulatory guidance on eConsent implementation to streamline multi-country DCTs and avoid fragmented processes. All variations in country-specific requirements in consent forms or signatures adds complexity, which need to be implemented and tested. Harmonisation will simplify the technical implementation process and ensure consistency. This includes standardisation of legal interpretations and requirements regarding signatures, such as the necessity of multiple signatures for GDPR and other purposes.

- **Implement long-term validity and storage solutions.**

Ensure that all PDFs requiring digital signatures are saved as PDF/A for long-term preservation. Additionally, implement the highest level of long-term validity checking (PAdES-B-LTA level) for all ICFs signed after a specified date. This will ensure that the signatures remain verifiable over time.

- **Develop backup procedures for eConsent.**

Establish backup procedures for scenarios where eConsent is blocked or signatures cannot be obtained. This includes having alternative methods remote methods such as via post. Back-up procedures may also be used for participants who do not have the digital literacy to navigate the eConsent process.

- **Ensure equitable accessibility of remote eConsent.**

Improve the accessibility of remote eConsent by addressing barriers such as the requirement for specific types of identification. For example, work with service providers to accept a broader range of identification documents, especially in regions where certain IDs are less common. This will help include a wider demographic. One can even consider if eIdentification is necessary according to local guidance; a qualified e-signature (QES) might not always be required.

- **Invest in comprehensive training and ongoing support for site staff.**

Equip clinical trial sites with the knowledge and resources they need to confidently guide participants through remote consent procedures. Ensure that staff receive thorough initial training and have access to continuous support, enabling them to address participant questions, navigate technical challenges, and deliver a smooth, participant-friendly consent experience.

Home shipment and collection

- **Optimise shipment frequency and kit assembly.**

Minimize participant burden by reducing the number of separate shipments while avoiding excessive storage requirements at home. Consider assembling multi-component kits for early visits but avoid sending all materials upfront if they will not be used for weeks or months. RADIAL showed that participants often misplaced or discarded unused kits, leading to unplanned resupplies. A phased approach, as in, sending critical materials initially and aligning subsequent shipments with protocol milestones, proved more effective.

- **Plan for IoT and EoT logistics early.**

Initial and final trial stages require special attention. At IoT, ensure timely delivery of all essential materials for screening and randomisation without overwhelming participants. At EoT, define clear processes for returning unused IMP, devices, and biological samples. RADIAL highlighted that unclear responsibilities for importer/exporter roles and lack of dry runs created delays and contractual challenges. Early planning, including customs and vendor agreements, mitigates these risks.

- **Integrate contingency and participant-friendly processes.**

Implement overage strategies for IMP to prevent treatment interruptions due to shipment delays or temperature excursions. Provide clear instructions and support for sample return and consider courier pick-up or home nurse visits when drop-off points are unreliable. RADIAL demonstrated that direct-from-participant collection, though costly, improved success rates and reduced participant burden.

Home nursing in DCTs

- **Standardise templates and contracts.**

Develop industry-wide templates for contracting with sites utilising external home nurse services., especially to clarify the delegation of tasks and oversight of home nurses and data sharing, which should account for both regulatory and site-specific requirements.

- **Carefully consider site experience and processes.**

Assess site experience, processes and use of internal or external nursing resources to ensure the appropriate level of support and training required to reduce oversight risks. Ensure investigators are comfortable integrating external home nurses into their practice as part of the site initiation visit. Less experienced sites should be provided with with clearly written communication and oversight plans with the home nurses.

- **Align training.**

Schedule site staff and home nurse training to allow time for setting up processes, and supplement it with refresher modules as close as possible to the first expected visit to reduce knowledge loss and maintain familiarity

- **Implement data privacy safeguards**.

Implement strict access control for any digital platforms used for transmitting participant contact information to home nurses and home nursing service providers, including audit trails and clear user role assignments.

- **Assign clear roles.**

Establish a clear definition of roles and responsibilities for all home nursing activities in the PI oversight documentation and ensure these are signed off before the first visit is scheduled. Ensure all

stakeholders, including couriers and IMP providers have written instructions/training and have clarity with regards to each other's roles.

Impact & KPIs

Patient accessibility and representativeness

- **Optimise online recruitment for diversity.**

Deploy online recruitment strategies thoughtfully to increase trial visibility and outreach to diverse populations, particularly underserved groups. Tailor online outreach carefully to ensure balanced representation.

- **Leveraging Local and Community Networks.**

Engage local healthcare providers (e.g., specialised physician or nurse networks) and community health workers as active trial stakeholders, enabling access and fostering trust in remote or underserved areas.

- **Identify and mitigate digital literacy barriers.**

Provide comprehensive digital literacy support and alternative participation methods to accommodate varying technological competencies and ensure equitable participation.

- **Monitor and report diversity metrics.**

Systematically collect, monitor, and transparently report demographic data of trial participants to assess diversity outcomes, identify gaps, and inform improvements. In RADIAL, participants in the remote arm lived further away from the clinical trial arm compared to the participants in the site-based conventional and hybrid arm.

Retention

- **Ensure research is of value to participants.**

Beliefs and perceptions about the value of the research and trustworthiness of the research team are balanced against the possible burden of taking part when people decide whether to participate in a particular trial. Early involvement of patients was identified as one way to gauge participant priorities.

- **Ensure participant experience aligns with expectations.**

Make sure that participants understand fully what they are agreeing to do in the trial. Consider that participants may feel overburdened by study tasks, especially if they are unfamiliar with the technology or online interfaces used.

- **Simplify participant activities.**

Minimising the number of devices and technological interfaces involved in data collection and uploading reduces the burden of trial participation. Simple DCT interfaces, such as study websites with clear directions, calls to action and concise text help to retain participants. Make it clear to participants why particular actions are required and what ‘behind-the-scenes’ activities are being carried out to achieve the study’s aims.

- **Maintain two-way communication with participants.**

DCTs are particularly susceptible to misunderstandings by trial participants because there are generally fewer opportunities to check understanding and explain the rationale behind trial activities. Regular contact with participants to enquire about changes in their condition and circumstances and the creation of interactive bulletins and interfaces may help with this.

- **Provide feedback to participants.**

Tools or interfaces that provide immediate feedback to participants on their condition, along with regular updates on trial progress, are highly valued by DCT participants and support retention. The ability of technology-enabled DCTs to give participants useful or interesting information they would not otherwise be able to access is especially appreciated by participants.

- **Offer flexibility in ways to participate where possible.**

Changes in an individual’s circumstances or values, especially during long-duration trials, may result in them choosing not to adhere to study activities or to withdraw entirely from the trial. DCTs may mitigate against such withdrawals or missing data by offering a degree of flexibility in ways to participate.

Carbon footprint

- **Embed carbon footprinting in DCTs from the beginning.**

From inception, embed carbon footprinting in DCTs. This includes prospectively capturing carbon emissions data on all aspects of the clinical trial. Understanding which elements contribute to the carbon footprint of a trial can help investigators identify opportunities to reduce trial carbon footprints. Planning to collect this data prospectively allows more accurate assessment of carbon footprint than trying to do this retrospectively.

- **Further develop tools for carbon footprinting of DCTs.**

We should continue to improve and develop tools that can measure the carbon footprint of DCTs with as much accuracy as possible.

Economic insights

- **Evaluate the added value of DCT elements in relation to costs.**

The feasibility and added value of the DCT elements should be considered in context of the study population. Relevant cost drivers to take into account are speed of enrolment, retention, overall trial timelines, and trial size. Trial size can be relevant, as some elements, like telemedicine or custom apps, have high upfront costs but scale well for large trials. Other costs, such as direct-to-patient IMP shipments or home diagnostics, increase with participant numbers. Consider opportunities to reduce initial costs over time through experience, centralised logistics, or reuse (see below), and evaluate if these weigh up against the added value for participants.

- **'Reduce, reuse, and recycle' technology.**

Minimise complexity and costs for sites and patients by having a minimal number of interfaces and processes, thus keeping the cost of training and required resources low. We suggest combining all digital technologies on one device or portal; limiting the number of vendors that manage third-party services; prioritising reuse or adaptations of proven solutions rather than creating new custom developments (e.g., standardise reusable templates and platforms across trials for eConsent).

- **Gain experience with DCT elements to reduce study personnel costs.**

Many study sites still have limited experience with decentralised elements. Therefore, time of study personnel for the set-up of DCT elements, and issue management during follow-up are expected to reduce in the future when they have more experience.

- **Centralise logistics.**

Centralise logistics management with a single depot where feasible, limiting costs related to inventory management and individual shipments.

Data quality

This page is still under development at the time of writing this report.

Patient Considerations & Involvement

Patient preferences

- **Incorporate patient preferences into future trial designs.**

We recommend clinical design teams to integrate patient preferences (and caregiver preferences in case of pediatric trials) for trial participation into the trial design. Teams should also take into account possible differences in preferences among people of, for example, different age or gender.

- **Consider implementing decentralised trial elements in future trials.**

Our research showed that participation in clinical trials that are either fully decentralised or hybrid is preferred over participation in site-based clinical trials in individuals with type 2 diabetes mellitus in Germany, Austria and the Netherlands. We recommend clinical trial design teams to consider implementing decentralised trial elements in future trials, taking into account the specificities of the therapeutic area of the trial.

Participant experience

- **Utilise validated and easy-to-use digital technologies and ensure interoperability.**

The use of digital technologies enables trial activities to be performed from the participant's home, which allows for more flexibility in trial participation, and can therefore have a positive influence on the participant's trial experience. When technology, which is often more present in DCTs, is not working, it can have a strong negative impact on the participant experience. Potential causes can be a malfunction of the device or increased time required for troubleshooting. We therefore advise trial design teams to deploy technologies that have not only been validated and tested to be user-friendly, but also to ensure their interoperability and compatibility with the wide array of combinations of hardware and operating systems encountered in the real-world, especially in a Bring-Your-Own-Device trial.

- **Provide clear information and support communication with trial staff.**

We found that both the provision and explanation of trial information and the competent and friendly interaction with trial staff, either remote or in-person, contributed to participants' overall satisfaction. As participants valued the support they received from trial staff in the RADIAL trial (telemedicine calls, phone calls, home visits, on-site visits, depending on the trial arm), we advise providing a communication method which allows participants to ask questions easily. Participants should know who to contact and when, especially when in-person trial visits are not scheduled. We recommend the use of simple and understandable lay language when providing information and notifying participants about the results of medical tests and future support after the trial.

- **Tailor trial activities to the participants' needs.**

We recommend involving patients or patient representatives upfront to discuss the feasibility of trial activities, as, e.g., working people may have different time resources available for trial visits or data collection as opposed to retired people. In addition, certain trial activities, such as taking a blood sample or measuring blood pressure as part of the physical examination, may be challenging for some participants to conduct themselves. In such cases we advise offering alternatives for participants, such as having a nurse visiting the participant at home to take these measurements.

Assessment & Approval

Overarching ethical considerations

- **Consider positive outcomes beyond direct therapeutic benefit.**

People participating in a DCT experience positive outcomes beyond the direct therapeutic benefit, Ethics reviews often emphasise the potential risks and burdens associated with DCTs, potentially overshadowing the direct and collateral benefits participants may experience, such as receiving medical devices, reduced travel time, or enhanced health literacy. We advocate for explicitly including these collateral benefits in ethical evaluations to make risk-benefit assessments more balanced, fair, and participant-centred.

- **Monitor the soft impacts of DCTs.**

The soft impacts of DCTs are difficult to measure or predict. These includes shifting responsibilities, changes in existing relationships within the healthcare and research context, new impacts on privacy, and trust. We also considered the broader soft impacts of digital technologies, such as how they shape behaviours, social interactions, and personal values. Recognising these influences. We recommend to monitor and document a broad range of effects and experiences as part of DCTs to align digitalisation ethically and practically with participant needs.

- **Give more attention to responsibility attribution and implementation through clear governance structures.**

The increasing use of digital health technologies and AI-driven systems in DCTs changes traditional oversight and responsibility structures and may diffuse responsibilities among multiple actors. Diffusion diminishes the ability of actors to fulfil responsibilities related to ethical conduct of trials. Clearer frameworks are required to effectively map responsibilities, address risks, and establish robust communication channels among stakeholders, ensuring accountability and efficient management of DCT approaches.

- **Use the four scenarios developed within Trials@Home.**

These scenarios also include accompanying advice for researchers on ways of mitigating challenges and proposals for adjustments of the regulatory framework. They outline four critical areas for ethical and responsible DCT implementation: enhancing participant-centricity through empowerment and reducing trial burdens via technology; careful and justified collection of real-world data; maintaining rigorous oversight to ensure participant safety; and clearly defining and effectively pursuing diversity goals within trial populations.

Health technology assessment awareness

- **Increase HTA bodies awareness on DCT approaches.**

This could be achieved through trainings and stakeholder engagement to help HTA assessors in their appraisal of study results that used DCT approaches.

- **Engage with HTA bodies early.**

As the EMA-HTAb Joint Scientific Assessment (JSA) is expected to play an important role in the future evaluation of trials for reimbursement, early engagement with HTA bodies is recommended to support decision-making and ensure acceptability of data generated through innovative approaches.

EU regulatory landscape

- **Harmonise across Member States.**

Harmonised implementation of all regulations from health authorities and ethics committees across the EU is needed. National-level variation hampers the conduct of CTs in a uniform way and requires tailored approaches in each country). A centralised overview of national-level variations, such as the HMA EMA Recommendation Paper on Decentralised Elements in Clinical Trials, should be regularly updated to provide support.

- **Interact with regulators early.**

As for any complex or non-standard trial, engaging with regulators early in the trial design process is crucial for the successful implementation of DCTs.

- **Consider where federal systems are in place.**

Federal systems may influence which DCT approaches can be implemented in a country, regardless of CTA approval.

Oversight & Clinical Management

Site staff readiness and training

- **Change reimbursement for site activities.**

Evaluate the applicability of the fees. When tasks are performed by third-party service providers, the fees can be omitted from site fees, such as using central pharmacy for drug dispensing and shipment. However, do calculate time for sites to request these activities and file necessary documents related to these tasks. Inevitably, the increased use of devices and tasks performed by participants, rather than site personnel, requires more time for training and troubleshooting when devices malfunction.

- **Assess site readiness for DCT elements.**

Evaluate the site's previous exposure to decentralised elements, such as remote study drug data monitoring and trial applications. We don't recommend to only select experienced sites, but sites that have less experience with decentralised elements require more time for contracting, set-up and training.

- **Consider digital literacy of site personnel.**

While it's the sponsor's responsibility to select and/or design user-friendly systems and adequately train the site to use these systems, it is inevitable that site personnel might need necessary digital skills to manage DCT elements effectively.

- **Ensure timely site contracting.**

Address potential delays in site contracting by clarifying the delegation of tasks and data processing responsibilities due to DCT elements early in the process. DCTs often involve multiple third-party service providers that carry out parts of the trial tasks, these should be clarified before contract negotiations and contracting templates should be adapted to include DCT elements.

Privacy and data protection

- **Address the heightened protection challenges in DCTs.**

DCTs amplify existing privacy risks and introduce added complexity. There is a lack of standardisation, data flows are complex, and the distinction between sponsors/sites and controllers/processors can become muddled.

- **Informed consent forms require extra attention.**

Participants must receive clear, accessible information about data flows and the involvement of various vendors. Participant information should be written in simplified language, adapted to the needs of a diverse participant base. Explaining new technologies used in DCTs may be particularly challenging and requires careful consideration to ensure comprehension.

- **Ensure robust protection of personal data in decentralised clinical trials, especially during escalations or disruptions.**

In DCTs, data sharing across multiple remote parties and platforms increases the risk of inadequate data minimisation and pseudonymisation practices. Clearly assess which decentralised vendors and remote staff require access to identifiable participant data. Standard pseudonymisation techniques should be consistently applied, with reinforced protocols during deviations from normal procedures.

- **Ensure appropriate safeguards for international data transfers.**

Data processing agreements with vendors and sub-processors handling data outside the EEA must include adequate protections. For transfers to the U.S., this includes using the EU Standard Contractual Clauses and applying additional safeguards, such as pseudonymisation.

PI responsibilities, oversight and safety reporting

This page is still under development at the time of writing this report.

Technology & Support

Technology components

- **Advocate for robust data standards.**

A standardised framework for real-world data and common data models would enhance consistency and reliability. Prioritise interoperability by design in technology platforms to enable seamless integration and analysis of diverse data sources. Prioritise interoperability by design in technology platforms to enable seamless integration and analysis of diverse data sources. Conduct targeted technology scans specifically aligned with planned DCT activities to avoid overly broad or irrelevant outcomes.

- **Provide structured training.**

Comprehensive pre-trial training should be provided for all stakeholders (site staff, home care teams, participants), focusing on practical technology use and a clear understanding of the trial processes.

- **Implement responsive technical support**.

Providing responsive, real-time technical assistance during the trial is essential to promptly resolve issues, minimize disruptions, and ensure data accuracy. This requires clearly defined communication channels to support continuous assistance, enabling swift escalation and resolution of complex problems. Maintaining short communication lines is critical—first-line support teams, including site staff and CRAs, should be equipped with the necessary technical knowledge to address issues immediately and report them effectively. Additionally, resources such as user guides and troubleshooting documentation should be readily accessible throughout the study to support timely problem-solving.

- **Equip study teams with foundational technical knowledge to effectively support site staff.**

Ensure study teams recognise and anticipate common technical challenges (e.g., device setup, data errors), and are trained to offer basic troubleshooting guidance, reducing the impact of minor technical disruptions. Define an escalation process to respective study team members can promptly refer complex technical issues to specialists, minimising disruption. Include trial-specific technology training for respective study team members during pre-trial activities, enabling them to effectively assist and empower the primary stakeholders without themselves becoming technical experts.

- **Select technology based on quality criteria.**

It is important to maintain systematic oversight of third-party vendor activities, as this ensures reliability and compliance. First, define and apply predefined quality criteria (e.g., interoperability, usability, scalability) during procurement to select optimal technologies.

- **Actively monitor trial technologies rigorously.**

Throughout the trial, continuously track technology performance through proactive risk management strategies to promptly detect and mitigate potential issues. Develop mitigation plans (alternative workflows) for technologies that underperform and define contingency plans to ensure continuity of activities without compromising data quality, patient oversight, or participant experience. Monitor compliance with regulatory requirements and manage vendor performance effectively. Regularly conduct vendor audits to maintain consistent quality and ensure ongoing compliance.

- **Develop a robust and risk-informed Bring-Your-Own-Device (BYOD) strategy.**

When implementing a BYOD approach in DCTs, it is essential to define clear technical compatibility requirements—covering both software and hardware—for study applications and any connected devices interacting with participants' personal smartphones. Early, geographically diverse field-testing using participant-sourced devices should be conducted to uncover potential regional or model-specific issues. To support effective troubleshooting, enable server-side logging and diagnostics to identify and resolve problems remotely. Study designs should incorporate fallback workflows, such as manual data entry options, that can be activated without initiating formal change requests. In cases where participant devices do not meet technical requirements, consider a hybrid provisioning model that provides study devices, while remaining mindful of the added burden posed by dual-device use. Finally, including a run-in phase to verify stable data flow before full enrolment can help ensure data integrity and reduce mid-study disruptions.

- **Enable site staff to practice with a dummy patient and trial devices.**

Allow sites hands-on access to the platform using test accounts and provide dummy hardware devices that replicate those used in the study. This helps site staff build familiarity with both the software and physical components, troubleshoot early, and reduce setup errors during actual participant onboarding.

- **Implement rigorous User Acceptance Testing (UAT) and dry run protocols for technology integration phases.**

When patient-facing technologies require independent home-based interaction, establish mandatory pre-enrollment testing phases incorporating simulated patient scenarios with comprehensive data collection and technology validation. This systematic approach enables site personnel to conduct end-to-end workflow rehearsals using test environments, facilitates early identification of technical vulnerabilities

and operational bottlenecks, and ensures robust verification of system functionality and safety protocols prior to live participant engagement, thereby mitigating protocol deviation risks and maintaining study data integrity throughout the trial lifecycle

Technical support system

- **Implement a centralised and scalable support framework.**

This is essential in DCTs to provide consistent, reliable assistance across study teams, site staff, CRAs, and collaboration with technology vendors. The framework should include a ticketing system, a searchable KB, clear internal and external workflows, and defined communication channels. This approach reduces operational burden, streamlines issue resolution, and enables effective coordination in complex multi-vendor environments, while also empowering site staff to support participants confidently and timely.

- **Engage the support team early in study planning.**

Involve the support team from the outset of DCT design, technology selection, and system testing. Early engagement helps identify potential risks, align support processes with operational needs, and build a system and team that can adapt to evolving trial demands.

- **Standardise ticket management and governance processes.**

Categorise tickets by issue type (e.g., platform, device, app, third-party tool) and assign priority levels. Conduct daily ticket reviews and weekly governance meetings to track trends, uncover training gaps, and follow-up on unresolved items. Log issues related to third-party technologies directly into vendor systems and proactively monitor resolution timelines. Escalate high-impact cases and incorporate vendor performance reviews into governance meetings. Improve ticket quality and submission efficiency by using structured templates to help users submit clear, and complete tickets. This improves resolution speed and reduces unnecessary follow-up by enabling better triage and more effective support.

- **Provide multilingual support options.**

Provide multilingual support via phone and scheduled live or remote video sessions, including onboarding walkthroughs, and device demo or troubleshooting calls. These formats help build user confidence and facilitate timely issue resolution.

- **Design an accessible and search-optimized KB.**

Use a familiar and intuitive format (e.g., internal wiki-style site) and optimize for searchability. Highlight high-traffic content (e.g., FAQs, troubleshooting guides) and ensure the KB is embedded in ticket workflows and training. Encourage users to consult the KB before raising tickets. Embed KB usage into onboarding and refresher training to reduce support load and empower self-service and -troubleshooting.

- **Simplify navigation across multiple tools.**

When systems are not integrated, offer a centralized access point or clearly organized links through the support system platform. This helps users navigate across technologies more easily and reduces delays in accessing information or assistance where needed.

- **Monitor helpdesk metrics for continuous improvement.**

Track metrics such as ticket volume, resolution times, and recurring issues to assess support effectiveness. Use issue trends and insights to refine user training, improve support workflows, and update KB content.

Introductory course on DCTs

The Trials@Home consortium developed a training for patients and patient organisations to optimise understanding of Decentralised Clinical Trial approaches (DCTs) in Europe. This online training has been created to introduce the concept of DCTs, and to explain how to design and run such trials and which technologies can be used for which decentralised activities.

The training is available on https://trialsathome.com/the-trialshome-course-on-dcts/ as well as on the online education toolkit of several patient organisations.